

Appln. No. 10/588,153  
Amdt. dated November 4, 2009  
Reply to Office Action dated May 8, 2009

#### REMARKS

The Office Action of May 8, 2009 has been carefully studied. Favorable reconsideration and allowance of the claims are respectfully requested.

#### I. Claim Status and Amendments

Claims 1-20 were pending in this when last examined. Claims 11 and 15-20 have been withdrawn as being directed to non-elected subject matter. Claims 1-10 and 12-14 have been examined on the merits and stand rejected. No claims have been allowed.

By way of the present amendment, claim 1 has been amended to incorporate the subject matter of claims 2-4 and 13, now cancelled. Further support for claim 1 can be found in original claim 1 and in the disclosure, for example, at page 7, lines 1-16 and at page 8, lines 6-20. Claims 5-8, 10, and 12 have been amended in a non-narrowing manner, to use correct punctuation. Claim 9 has been amended to be consistent with claim 1. No new matter has been added.

Claims 2-4, 11, 13, and 14 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

Of the elected and examined claims, claims 1, 5-10, and 12 will remain pending upon entry of this amendment, and these

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claims define patentable subject matter warranting their allowance for the reasons discussed herein.

It should be noted that the above claim amendments address matters of form only and they amend independent claim 1 to incorporate the subject matter of dependent claims already under examination. For instance, amended main claim 1 now incorporates the subject matter of original claims 13 and intervening claims 2-4. Accordingly, the present amendment does not present any new issues for consideration and/or search as these claims correspond to subject matter already considered in the last Office Action. Therefore, Applicants take the position that any new art based rejection of amended claim 1 should properly be brought in a non-final Office Action since the present amendment cannot be construed to require new grounds for rejection.

## **II. Election/Restriction**

On pages 2-3 of the Office Action, the Examiner provides reasons for maintaining the restriction requirement.

First, the Examiner argues that the inventions of the different groups lack unity of invention on the grounds that they do not make a contribution over the prior art for the reasons set forth in the art rejections in the instant Office Action. Applicants respectfully traverse this position for the reasons set forth below with respect to the arguments against the prior art rejections.

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Second, the Examiner argues that claim 1 is not a generic claim, because it conflicts with claim 11. Applicants disagree. Nonetheless, Applicants have cancelled claim 11 without prejudice or disclaimer by way of the present amendment, thereby obviating the Examiner's second argument for maintaining the restriction requirement.

Thus, as the Examiner's reasons for maintaining the restriction requirement are untenable, the requirement should be withdrawn and all of the claims should be examined together.

### **III. Sequence Rules**

On page 2, the Examiner objects to the application on the basis that it fails to comply with the Sequence Rules. The Examiner notes that the specification, at pages 17 and 22, contains sequences lacking a sequence identifier. The Examiner notes that Figures 1, 4, 5, 6, 10 and 12 show sequences lacking a sequence identifier either in the drawing itself or the Brief Description of the Figures in the disclosure.

In reply, Applicants herein amend the application to comply with the USPTO's Sequence Rules. Specifically, Applicants amend the specification to include a new Sequence Listing in paper and computer readable forms (CRF) and to insert sequence identifiers where appropriate. The paper copy and CRF copy of the Sequence Listing are the same and no new matter has been added. The Sequence Listing was generated to include the sequences found

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in the originally filed application using PatentIn version 3.5 (September 2007). The Sequence Listing was run through the USPTO Checker software (Version 4.4.0) (October 25, 2005) and no errors were found.

Under USPTO rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe

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may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

It is respectfully submitted that the application complies with the Sequence Rules under C.F.R. §§ 1.821-1.825, and therefore, the above noted objection should be withdrawn.

#### IV. Anticipation Rejections

##### Travascio et al.

Claims 1-4 and 7-9 have been rejected under 35 USC 102(b) as being anticipated by Travascio et al. for the reasons on pages 4-5 of the Office Action. This rejection is respectfully traversed.

To start, it should be noted that claim 1 has been amended to incorporate subject matter from claim 13 (now

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cancelled), which was not included in this rejection. In doing so, claim 1 now specifies that the analyte to be detected is a nucleic acid. For this reason, the present amendment obviates this rejection.

Again, Travascio et al. does not disclose detecting a nucleic acid. Moreover, Travascio et al. fails to disclose a method for the determination of a nucleic acid in a sample which comprises the steps of contacting a catalytic polynucleotide, which is a DNAzyme complexed with hemin and having a peroxidase activity, with the sample so that the catalytic polynucleotide may bind to the nucleic acid; providing assay conditions such that said catalytic polynucleotide produces an optically detectable signal in the presence of the nucleic acid; and detecting said signal, thereby determining the presence of the nucleic acid in the sample, as required in claim 1.

Instead, Travascio et al. merely shows the peroxidase activity of a DNA-hemin complex. However, this does not teach, nor does it suggest, a detection system for detecting a nucleic acid. Instead, it relates to a specific experiment demonstrating peroxidase activity of the DNA-hemin complex examined. The Examiner takes the position that since the DNA sequence binds hemin, which is only active after this binding, hemin is considered to be the analyte detected in Travascio et al. Indeed, the Examiner, at page 9 lines 1-3, and 13-15 of the

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Office Action, equates Travascio et al. as disclosing a method of detecting hemin in its broadest interpretation. However, this is not the same as, nor does it suggest, a method for detecting a nucleic acid, as required in claim 1. Travascio et al. does not disclose or suggest using the DNA-hemin in a method to detect a nucleic acid in a sample. Again, the amendment to claim 1 emphasizes this distinction.

For this reason, it should be clear that Travascio et al. fails to disclose each and every feature of claim 1. Thus, claim 1 and all claims dependent thereon are novel over Travascio et al. Therefore, the above anticipation over Travascio et al. is untenable and should be withdrawn.

Usman et al.

Claims 1-3, 5, 7, 9 and 13 have been rejected under 35 USC 102(b) as being anticipated by Usman et al. (US2002/0102568) for the reasons on page 5 of the Office Action. This rejection is respectfully traversed.

It should be noted that claim 1 has been amended to incorporate subject matter from claim 4 (now cancelled), which was not included in this rejection. In doing so, claim 1 now specifies that the catalytic polynucleotide is complexed with hemin. Thus, the present amendment overcomes this rejection by amending the independent claim to incorporate the subject matter

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of a claim not included in the rejection. Withdrawal of the rejection is requested.

Lu et al. (US2003/0215810)

Claims 1, 2, 7, 9 and 12 have been rejected under 35 USC 102(b) as being anticipated by Lu et al. (US2003/0215810) for the reasons on pages 6-7. This rejection is respectfully traversed.

Lu et al. teaches detection of ions. The present amendment emphasizes that the analyte to be detected is a nucleic acid. In doing so, claim 1 has been amended to incorporate subject matter from claim 13 (now cancelled) and also claims 3 and 4 (both now cancelled), which were not included in this rejection. Thus, the present amendment overcomes this rejection by amending the independent claim to incorporate the subject matter of a claim not included in the rejection. Withdrawal of the rejection is requested.

Lu et al. (US 6,706,474)

On page 7, the Examiner rejects claims 1, 2, 5 and 9 under 35 USC 102(b) as being anticipated by Lu et al. (US 6,706,474). This rejection is respectfully traversed.

Lu et al. teaches detection of ions. Again, the present amendment emphasizes that the analyte to be detected is a nucleic acid. In doing so, the present amendment overcomes this rejection by amending the independent claim to incorporate the



subject matter of a claim not included in the rejection.  
Withdrawal of the rejection is requested.

**V. Obviousness Rejections**

Travascio et al. in view of Kawaguchi et al.

Claims 1-9 have been rejected under 35 USC 103(a) as being obvious over Travascio et al. and further in view of Kawaguchi et al. (US2002/0076696) for the reasons set forth on pages 8-9. This rejection is respectfully traversed.

Again, the Examiner's position is that Travascio et al. discloses a method of detecting *hemin* [page 9 lines 1-3, and 13-15, Office Action], not a nucleic acid. The arguments set forth above with respect to Travascio et al. are reiterated herein by reference. Again, the present amendment to claim 1, which clarifies that the analyte to be detected is a nucleic acid, should overcome the rejection. In other words, claim 1 has been amended to incorporate the subject of claims not included in this rejection. For this reason, the rejection is untenable and should be withdrawn.

Usman et al. in view of Lansdorp et al.

Claims 1-3, 5, 7, 9, 10, 13 and 14 have been rejected under 35 USC 103(a) as being obvious over of Usman et al. in view of Lansdorp et al. (US2003/0022204). This rejection is respectfully traversed.

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The present amendment to claim 1, and which clarifies that the catalytic polynucleotide is complexed with hemin as stated in previous dependant claim 4, should render this rejection moot. In other words, claim 1 has been amended to incorporate the subject of claims not included in this rejection. For this reason, the rejection is untenable and should be withdrawn.

**VI. Conclusion**


Having addressed all the outstanding issues, this paper is believed to be fully responsive to the Office Action. It is respectfully submitted that the claims are in condition for allowance, and favorable action thereon is requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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**APPENDIX:**

The Appendix includes the following item(s):

- Sequence Listing in "txt. format".